Decision Memo for Home Biofeedback For Urinary Incontinence (CAG-00118N)

Decision Summary

CMS will reaffirm its existing national noncoverage policy for home biofeedback devices in the treatment of urinary incontinence. The medical literature is not sufficient to reliably conclude that the use of home biofeedback devices is reasonable and necessary to treat urinary incontinence.

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Decision Memo

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Subject: Coverage Decision Memorandum for Home Biofeedback for Urinary Incontinence
DATE: March 1, 2002

This decision memo addresses a request for reconsideration of the national coverage decision for biofeedback for the treatment of urinary incontinence received from DesChutes Medical Products, Inc. DesChutes requested that we change the current noncoverage policy to cover the *fria* system, a pneumatic biofeedback device for use at home to treat women with stress, urge, or mixed urinary incontinence. The request indicated that the device can be used as a stand-alone therapy at home or adjunct to a physician's guidance or service. Use of biofeedback devices are covered in the office, or other facility setting, under certain circumstances. Use at home is currently noncovered. DesChutes submitted 12 published articles, one of which evaluated the use of a biofeedback device as stand-alone therapy at home and a second study that evaluated treatment with home biofeedback combined with office sessions under a practitioner's guidance. We initiated a reconsideration to address these issues.

This memo serves four purposes: (1) briefly outlines the use of biofeedback for the treatment of urinary incontinence; (2) reviews the history of Medicare's coverage process on the use of biofeedback for the treatment of urinary incontinence; (3) presents and analyzes the relevant scientific literature on home biofeedback therapy for the treatment of urinary incontinence; (4) delineates the reasons for affirming our national noncoverage policy for the use of home biofeedback devices in the treatment of urinary incontinence.

Clinical Background

Urinary incontinence refers to the involuntary loss of urine. Approximately 17 million adults in the United States suffer from urinary incontinence, with nearly half of nursing home residents having some degree of incontinence. Women are twice as likely to be affected as men. Several factors account for this gender difference: pregnancy and childbirth, menopause, and the structure of the female urinary tract. Nearly 35% of female Medicare beneficiaries and 25% of male beneficiaries are estimated to suffer from urinary incontinence.

Although the prevalence of incontinence increases with age, incontinence is not a normal consequence of aging. It is treatable, and often curable at all ages. In women, incontinence usually occurs as a result of problems with the muscles that help control the release of urine. In men, incontinence usually occurs as a result of prostate surgery.

Types of Incontinence

There are various types of urinary incontinence. The two most common types are stress and urge.

Stress incontinence refers to involuntary loss of urine due to inadequate urethral pressure. The patients experience urine loss during coughing, sneezing, or physical exertion.

Urge incontinence refers to the involuntary loss of urine due to abnormal bladder contractions (e.g. detrusor instability). It is often associated with a sudden, strong desire to urinate. Urge incontinence occurs with little warning and large amounts of urine are lost.

*Mixed incontinenc*e is the term used when features of both stress and urge incontinence coexist.

Post-prostatectomy incontinence is a common condition among elderly men, and results from the treatment of prostate cancer or benign prostatic hypertrophy. It can manifest as stress or urge incontinence.

Functional incontinence refers to incontinence resulting from such factors as medications, infections, cancer, trauma, diverticuli, and fistulas.

The specific type of incontinence can be diagnosed by clinical or urodynamic testing.

Treatment Options

Treatment options include behavioral modifications (e.g., bladder training and pelvic muscle exercises), medications, vaginal cones, sacral nerve stimulation, electrical and magnetic stimulation, as well as surgery. A staged approach to treatment is recommended for most patients, beginning with the most conservative techniques, progressing to more invasive treatments if initial measures are unsuccessful. The Agency for Heathcare Research and Quality, formerly the Agency for Health Care Policy and Research (AHCPR), issued the most recent guidelines for the management of urinary incontinence in 1996.[1]

Biofeedback in conjunction with pelvic muscle exercises (PME) has been used for several decades as an intervention to improve bladder control. Typically, the patient receives coaching from a practitioner in an office or outpatient setting. Patients are requested to supplement their practitioner-guided sessions with home exercises.

As stated in the October 2000 decision memorandum announcing our intent to cover biofeedback in the treatment of urinary incontinence when used by a practitioner in an office or other facility setting,[2] biofeedback-assisted pelvic muscle exercises incorporate the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of pelvic floor muscle exercises.

Biofeedback in conjunction with PME targets skeletal muscles that are under voluntary control. Some patients have difficulty identifying, controlling, and coordinating the function of pelvic floor muscle groups through verbal instructions or are uncomfortable with digital palpation to assess the adequacy of muscle contractions. With biofeedback, these exercises are performed with simultaneous electromyographic feedback given to the patient to help facilitate awareness of the state of muscle contraction.

History of Medicare's Biofeedback Coverage Policy and Timeline of Recent Activities

Medicare's national coverage policy for biofeedback for the treatment of urinary incontinence is found in Section 35-27.1 of the Medicare Coverage Issues Manual. It states:

Biofeedback therapy for the treatment of urinary incontinence (Effective for services performed on or after July 1, 2001.) This policy applies to biofeedback therapy rendered by a practitioner in an office or other facility setting.

Biofeedback is covered for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Biofeedback-assisted PME incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of PME.

A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

Home use of biofeedback therapy is not covered.

Coverage Request

In August 2001, DesChutes Medical Products, Inc. requested that the Centers for Medicare and Medicaid Services (CMS) reconsider its noncoverage policy for home use of biofeedback devices in the treatment of urinary incontinence. The company submitted new data to support its request for coverage of home biofeedback devices in the treatment of urinary incontinence.

Recent Developments and Timeline of Activities

August 14, 2001	Request received.
October 10, 2001	Letter sent to requestor asking for clarification of issues raised in the application and information necessary to complete request.
October 24, 2001	Clarification on points raised in October 10 letter received, as well as information necessary to complete request.
November 21, 2001	CMS accepts formal request after completing initial survey of literature and determining that the request is complete.

Medicare law provides coverage for broad categories of benefits, including durable medical equipment (DME). A specific item or service must fit into one of these benefit categories to be eligible for medicare coverage. The *fria* biofeedback device meets the criteria to be classified as DME outlined in Section 2100.1 of the Medicare Carrier Manual (MCM) and 42 CFR 414.202. The definition of DME equipment is that which (a) can withstand repeated use, (b) primarily and customarily used to serve a medical purpose, (c) generally is not useful in the absence of illness or injury and (d) is appropriate for use in the home.

FDA Status

DesChutes Medical Products, Inc. received 510(k) FDA clearance for its home biofeedback system on March 1, 2000. The Reflex Treatment System, which was subsequently renamed *fria,* was approved for over-the-counter-use in the treatment "of stress incontinence and/or urge incontinence in females." The FDA's clearance was based on a predicate device that is also marketed by DesChutes, the PeriPumP, a device to treat "mild incontinence" in men and women.[3]

Summary of Evidence

CMS previously defined biofeedback for the treatment of urinary incontinence as pelvic muscle exercises incorporating the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone to the patient and assist her/him in the performance of such exercises. Although this definition was used in reference to biofeedback training performed in a physician's office, it would also apply to a home-based biofeedback program. The requestor produces a device, the *fria* home biofeedback pneumatic device, that is a self-taught, non-supervised system for treating urge, stress and mixed urinary incontinence. In researching the literature, CMS sought out all clinical studies on home biofeedback devices for treating urinary incontinence, not only articles addressing the *fria* device.

The requestor supplied CMS with a notebook that included an excerpt from the AHCPR guidelines, an e-mail outlining the research protocols of a study underway on females in the military, and 12 published articles. The AHCPR did not address home biofeedback specifically. One article (Smith et al. 2000) investigated the *fria* device and one (Susset et al. 1990) evaluated home biofeedback with office sessions. The following is a breakdown of the remaining 10 articles:

- one (Burgio et al. 2000) discussed home biofeedback combined with drug therapy for the treatment of urinary incontinence;
- three (Burgio et al. 1986, Sherman and Davis 1997) investigated biofeedback but not in the home setting;[4]
- two (Bump et al. 1991, Morkved and Bo 2000) discussed pelvic floor exercises only and did not investigate biofeedback;
- three (Brown et al. 2000, Nygaard et al. 1994, Olsen et al. 1997) were concerned with epidemiologic aspects of urinary incontinence;
- one was a review article (Bo and Berghmans 2000); and

- one (Fantl et al. 1996) was a practice guideline and did not assess home biofeedback.

CMS performed a Medline search in an attempt to identify additional articles. The keywords, "urinary incontinence," "home," and "home biofeedback" were used. This search yielded five publications. One was the article by Smith et al., referenced above. Of the other four articles, one dealt only with pelvic floor exercises (Elia and Bergman 1993), one was a review article (Payne 1998), and two investigated behavioral therapy in adults with incontinence (Bear et al. 1997 and McDowell et al. 1999). The study by Bear et al. (1997) stated that pelvic muscle exercises with biofeedback was one of three behavioral techniques used as part of their incontinence treatment program (which also included self-monitoring and scheduling regimens). This study included only six patients in the treatment group but did not indicate whether biofeedback was used in the treatment of any of the six patients. Thus, the studies by Smith et al. (2000), which used the *fria* system manufactured by the requestor, and Susset et al. (1990) were the only identified articles that evaluated home biofeedback in the treatment of urinary incontinence.

The Smith et al. case-series investigated the use of a self-directed home biofeedback treatment system in otherwise healthy women with symptoms of stress, urge and mixed incontinence. Women were recruited in one of three manners: through a lecture on urinary incontinence sponsored by a local medical center; at a national incontinence symposium; and through brochures left at an athletic club. A total of 55 women participated in the study, aged 25 to 81 years. To be included in the study participants had to be women with symptoms of stress, urge or mixed urinary incontinence, have no history of neurologic problems such as stroke, Parkinson's disease or multiple sclerosis, have intact cognition, and commit to the 16-week behavioral program.

Subjects underwent an initial evaluation that included a self-reported continence assessment, a 24-hour bladder and fluid-intake diary, severity index survey for stress and urge incontinence, and assessment of pelvic floor strength using the biofeedback device. Subjects were then mailed the treatment system. This consisted of an eight-minute educational/motivational video, journal for documentation, and a pneumatic sensor to measure pelvic muscle contractions. Patients were also given the number to a toll-free phone support line and web site address. Subjects were asked to perform the pelvic exercises in five-minute sessions three times a day for 16 weeks. The pneumatic sensor provided resistance levels that could be adjusted as pelvic strength increased. Once enrolled, the patients were asked to complete a data sheet of their status every two weeks. At the end of weeks eight and 16 they were asked to complete a continence assessment, 24-hour bladder/fluid intake diary and urge and stress severity survey. The authors did not describe what data was collected with the bi-weekly data sheet. The authors also stated that a final program evaluation was completed at week 16, but they did not state what that entailed.

Both the stress and urge severity indices used in this study were devised by the authors. They were self-rating scales that allowed the subjects to rate the severity of their symptoms. The authors stated that psychometric evaluation of these indices had not been completed, thus, the validity of these questionnaires is unclear.

Forty-four of the 55 women (80%) completed the 16-week program. Of the 11 withdrawals, four were for medical reasons, one was lost to follow-up, and six were for non-medical reasons. Of the withdrawals for medical reasons, one was for cystitis, one was for yeast infection, one was due to alcoholism, and one was listed as due to "illness." It is not clear if the vaginal sensor played any role in the development of the genitourinary conditions that lead to withdrawal. The age distribution of only the 44 women completing the study was provided. The breakdown was: 16% (7/44) were < 40 years; 57% (25/44) were 41-60 years; and, 27% (12/44) were >60 years. Of the 44 subjects, seven had stress incontinence, eight had urge incontinence, and 29 had mixed incontinence.

According to the article, at the end of the 16-week study, 43% (19/44) of subjects reported being dry (dry was defined as zero leaks per day). The study also reported that an additional 39% of patients (16/44) had a 50% or greater reduction in either leaks per day or voids per day by week 16. The study did not specifically state the number of subjects failing treatment, nor did it define what a treatment failure was considered to be. Little to no information was provided about the subjects' clinical course or whether or not they had been appropriately trained on and had previously failed a course of PME alone to determine if the reported improvement was related to the addition of biofeedback.

Of the patients with either stress or mixed incontinence, the mean number of leaks per day at the start of the study was 2.9. This decreased to 1.1 leaks per day by week 16. Similarly, among the patients with either urge or mixed incontinence, the mean number of voids per day was 10.8 at the start of the study, and decreased to 8.1 by week 16. The stress severity index (as determined by the authors' survey) decreased from 12.9 at week one to 4.6 by week 16 ($p<0.001$), and the urge severity index also decreased significantly over the same time period from 12.4 to 5.5 ($p<0.001$).

A breakdown of the results based on patients' age showed that while the number of leaks/day and voids/day decreased in all age groups, the greatest decrease was seen in the youngest age group (40 years or younger). The raw data showed the middle group, aged 41-60 years, had a reduction of leaks or voids per day less than the youngest group, but greater than the oldest group (over 60 years). The table below lists these data:

	<40 years	**41-60 years**	**>60 years**
Leaks/day week 1	3.4	2.9	2.7
Leaks/day week 16	0.7	0.7	1.9
Voids/day week 1	12.1	11.1	9.1
Voids/day week 16	8.1	8.3	7.8

The authors stated that there was a significant difference in improvement between the youngest and oldest age groups (p=0.02). They did not state, however, if the reduction in leaks or voids per day was significant within each group.

Estrogen use and prior bladder surgery did not appear to effect the outcome in patients with stress incontinence. There was no significant difference in improvement of leaks/day between patients taking and not taking estrogen (p=0.62). Likewise, prior bladder surgery did not effect the number of leaks per day (p=0.37). The effect of estrogen use or prior bladder surgery on urge incontinence (i.e., voids/day) was not reported.

In the Susset et al. case-series study, 18 women (ages 29 to 70) with urinary incontinence received weekly office sessions for six weeks and instructions to use a biofeedback device at home for 15 minutes twice each day. The device consisted of an air inflated vaginal probe connected to a small electrically powered box. Three of the patients dropped out of the study, one of whom was 80 years old and did not care to use an intravaginal probe. Twelve of the remaining 15 patients (80%) reported a subjective cure rate, while the other three subjects reported 75%, 65%, and 25% improvement. Objective measurements with the pad test found that 13 of the 15 patients (87%) had a negative test at the end of the six weeks. Thirteen patients had between 3 to 14-fold improvement in intravaginal pressure. Patients were called 5 to 10 months after the treatment. Of the 12 subjective cures, 9 who continued to perform exercises at home reported that they had no recurrence of incontinence. Objective tests of incontinence were not performed.

CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. § 1869(f)(1)(B). In order to be covered by Medicare an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

We have fully examined the medical and scientific evidence submitted with the request for reconsideration. As described below, the scientific evidence is not adequate to conclude that the use of home biofeedback devices for the treatment of urinary incontinence is clinically effective, and, therefore, is not reasonable and necessary for treating urinary incontinence or to improve the functioning of a malformed body member.

Only two articles were identified that addressed biofeedback delivered in the home setting for the treatment of stress, urge or mixed urinary incontinence (Smith et al. 2000 and Susset et al. 1990). While the authors of the Smith et al. study reported that patients could improve their symptoms of urinary incontinence with the self-directed home system they tested, methodologic problems with this study call the validity of their conclusions into question. Of most concern was the study's lack of a comparison group, patient selection and data collection biases, failure to prospectively define the outcome measures, and failure to state prospectively how patient attrition would be handled in analysis of the study's results. Other less serious flaws were also noted, including problems with the inclusion criteria, differences in success rate based on patients' age, questions about the validity of the severity indices used, and lack of long-term follow-up.

This study was a case-series with no comparison group. Without a control-group, it is difficult to conclude that any improvement seen was due to the home biofeedback device and not some other factor. An appropriate comparison or control group would have been given instructions on pelvic muscle exercises, but would not have used the device under study. Case series articles can serve a purpose, especially in the study of very rare diseases where enrolling enough patients in a clinical trial would be very difficult, or in situations where the withholding of treatment could be deemed unethical. However, stress, urge and mixed urinary incontinence are not infrequent problems. Smith et al. themselves reported that urinary incontinence affects approximately 25 million Americans. Therefore, patient enrollment should not be a problem in incontinence studies, and the use of control groups is not unethical in this non-life-threatening condition.

Potential patient selection bias is also a problem with this study. The authors' method of recruitment (via lecture at a local hospital, national symposium, and brochure placed at a local health club) is not population-based, and may have been biased towards enrolling highly motivated and healthy subjects. In addition, the study's demographics showed that 73% of the subjects who completed the 16-week study were 60 years of age or younger. This speaks to the issue of external validity of the study. Of special interest to CMS is the ability to relate a study's findings to the Medicare population. The younger age of the population studied herein, coupled with the overall good health of the subjects, makes it unclear if these results can be extrapolated to the Medicare population.

The results reported relied on the patients collecting their own data, i.e., number of voids or leaks per day and results of severity indices. Such data collection is especially subject to reporting bias. Patients may be more motivated to report success with something they perceive as possibly treating their condition. This speaks, yet again, to the need for a comparison group. Initial evaluation included assessment of pelvic floor strength using the pneumatic sensor device. This was at least one piece of qualitative data that could be more objectively gathered and compared over time. The authors did not report what the baseline pelvic floor strength was, nor did they repeat assessments of pelvic floor strength later in the study. The treatment system, as the authors stated, included pelvic muscle exercises. Thus, measuring pelvic floor strength seems integral to assessing response to this treatment program, and if done at baseline and again as the study progressed, could have provided more objective data.

The authors did not prospectively define what treatment outcomes would be measured. Results were presented with two scenarios as successful outcomes - "dry" and >50% reduction in number of leaks or voids per day. In addition, there is no mention of what constituted a treatment failure. Defining at the outset what measures would be used to assess success and failure would have provided a better understanding of whether the study's objectives had been achieved.

The final serious flaw with this study was the failure to prospectively define how subject attrition would be handled in the data analysis. This is an important issue since 20% (11/55) of the enrolled subjects withdrew from the study prior to completing the relatively short 16-week course of therapy. Other than stating the reasons for withdrawal, the authors did not give any further information on the status of these 11 subjects. Data was not provided on the age or type of incontinence in these patients. It would have been especially useful to know the ages of these patients. For example, were older subjects more likely to withdraw as compared to younger patients? Data on the progress these patients were making prior to their leaving the study would also have been helpful.

The study's inclusion criteria were also a possible source of bias. Subjects did not have a diagnosis of incontinence verified by a clinician; they only had to self-report symptoms of stress, urge or mixed urinary incontinence. Less serious problems included the failure to provide a list of what the reported incontinence symptoms were. In addition, patients with a history of neurologic illness, such as Parkinson's disease, stroke or multiple sclerosis were excluded. The absence of these problems, however, was not independently confirmed, nor was the list of possible excluding neurologic conditions completely delineated. Finally, the authors noted that intact cognition was an inclusion criterion, but how this was determined was not specified.

While the results showed a reduction in the number of leaks or voids per day in all three age groups, the reduction was greatest for the 40 and younger group followed by the 41 to 60 age groups. Reduction in leaks or voids per day was least for those subjects older than 60 years. The authors stated that there was a significant difference in the results between the youngest and oldest age groups. What they do not state is if the reduction within each age group was significant. This also speaks to the applicability of these findings to the Medicare population. If the only significant benefit with this therapy is seen in younger women, then its usefulness in elderly Medicare beneficiaries is questionable.

As the authors rightly point out, incontinence is a quality of life disorder and cure rate may not be as important as improvement rate. To help assess the severity of the participant's symptoms, and any change affected by the treatment, the authors developed a severity of index scale for stress and urge incontinence. Such indices can be very useful tools in measuring quality of life, although they also are subject to bias as a result of their own subjectivity. Such scales are validated through independent psychometric testing; however, as the authors stated, their severity scales have not been fully validated.

The results (i.e., number of patients reported as "dry" and reduction in number of leaks/voids per day) are presented at week 16 only. There is no information on how quickly patients progressed to these outcomes, nor are there data on maintenance of such outcomes. Do patients need to continue the daily program to see continued results and do such results continue beyond a few months? A study with longer follow-up built into the protocol would be useful to answer these questions.

The Susset et al. case-series study possesses many of the same serious flaws as the Smith et al. trial. In Susset et al., potential patient selection bias is a problem. Recruitment methods and inclusion and exclusion criteria were not reported. There was also no comparison group. As a result, we do not know if use of the biofeedback device and PME at home with office sessions offered any benefit over practicing only the PME at home with office sessions. Notably, the authors state that "[a] 30-minute weekly office session was essential to maintain incentive and reinforce their will to do the exercise." Of course, Medicare already covers office-based therapy under certain circumstances. In addition, it was not reported whether or not the patients had previously failed a trial of PME without biofeedback. Patients may have improved with exercise alone without the use of biofeedback. Also, subject attrition was not addressed. If the patients who dropped out of the study were included as treatment failures, only 67% and 72% of the patients would have experienced subjective and objective cures, respectively. Finally, at least one patient was 70 and one was 29, but the ages of the remaining subjects were not reported. Therefore, it is not known whether the results of this study are applicable to the elderly Medicare population.

While the Smith et al. and Susset et al. trials suggest that home biofeedback systems for treating stress, urge and mixed urinary incontinence warrant further study, we cannot reliably conclude that the use of a home biofeedback device with or without office sessions is clinically effective due to the serious methodological flaws in these studies, and, therefore, the use of a home biofeedback device for the treatment of urinary incontinence in Medicare beneficiaries is not reasonable and necessary. A randomized, controlled clinical trial, drawing on a Medicare representative population would be better able to support the use of home biofeedback devices in treating this condition. It will be useful in assessing the validity of such trials if they have prospectively defined treatment protocols and outcomes, use validated outcome instruments, and provide longer follow-up.

DECISION

CMS will reaffirm its existing national noncoverage policy for home biofeedback devices in the treatment of urinary incontinence. The medical literature is not sufficient to reliably conclude that the use of home biofeedback devices is reasonable and necessary to treat urinary incontinence.

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1 Urinary Incontinence in Adults: Acute and Chronic Management. Clinical Practice Guideline, No. 2. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, Department of Health and Human Services, 1996 Update.

2 Decision Memorandum on Biofeedback for Treatment of Urinary Incontinence (CAG-00020) can be found at http://www.cms.hhs.gov/ncdr/memo.asp?id=12.

3 Although a device must receive FDA clearance to be eligible for Medicare coverage outside of a clinical trial, FDA approval or clearance does not alone entitle that device to coverage. The device must fall under a Medicare benefit category and determined to be reasonable and necessary by CMS. CMS has the authority to conduct a separate assessment of a device's appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries (*see e.g.*, 60 FR 48417, 48420 (September 19, 1995)). As we stated in 66 FR 58788, 58797 (November 23, 2001), "[t]he criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug, and Cosmetic Act is significantly different from the scientific evidence we consider in making "reasonable and necessary" determinations under Medicare. FDA does not require clinical data or outcomes studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare evidence-base NCDs consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a substantial equivalency approval under section 510(k) of FDA is not sufficient for making determination concerning Medicare coverage."

4 Notably, the Sherman and Davis study failed to show that biofeedback provided significantly increased benefits as compared to PME with office-based instruction alone.

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Bibliography

Bear M, et al. Home-based management of urinary incontience: a pilot study with both frail and independent elders. *Journal of Wound, Ostomy and Continence Nursing* 1997;24(3):163-171.

Bo K, Berghmans LCM. Nonpharmacologic treatments for overactive bladder-pelvic floor exercises. *Urology* 2000;55(Supplement 5a):7-11.

Brown JS, et al. Urinary incontinence: does it increase risk for falls and fractures? *Journal of the American Geriatrics Society* 2000;48(7):721-725.

Bump RC, et al. Assessment of kegel pelvic muscle exercise performance after brief verbal instructions. *American Journal of Obstetrics and Gynecology* 1991;165(2):322-329.

Burgio KL, et al. The role of biofeedback in kegel exercise training for stress urinary incontinence. *American Journal of Obstetrics and Gynecology* 1986;154(1):58-64.

Burgio KL, Locher JL, Goode PS. Combined behavioral and drug therapy for urge incontinence in older women. *Journal of the American Geriatrics Society* 2000;48(4):370-374.

Elia G, Bergman A. Pelvic muscle exercises: when do they work? *Obstetrics & Gynecology* 1993;81(2):283-286.

McDowell BJ, et al. Effectiveness of behavioral therapy to treat incontinence in homebound older adults. *Journal of the American Geriatrics Society* 1999;47(3):309-318.

Morkved S, Bo K. Effect of postpartum pelvic floor muscle training in prevention and treatment of urinary incontinence: a one-year follow up. *British Journal of Obstetrics and Gynecology* 2000;107:1022-1028.

Nygaard IE, et al.Urinary incontinence in elite nulliparous athletes. *Obstetrics & Gynecology* 1994;84(2):183-187.

Olsen AL, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstetrics & Gynecology* 1997;89(4):501-506.

Payne CK. Biofeedback for community-dwelling individuals with urinary incontinence. *Urology* 1998;51(Supplement 2A):35-39.

Sherman RA, Davis GD, Wong BA. Behavioral treatment of exercise-induced urinary incontience among female soldiers. *Military Medicine* 1997;162(10):690-694.

Smith DB, Boileau MA, Buan LD. A self-directed home biofeedback system for women with symptoms of stress, urge and mixed incontinence. Journal of Wound, Ostomy and Continence Nursing 2000;27(4):240-246.

Susset JG, Galea G, Read L. Biofeedback therapy for female incontinence due to low urethral resistance. *Journal of Urology* 1990;143(6):1205-1208.

Urinary Incontinence in Adults: Acute and Chronic Management. Clinical Practice Guideline, No. 2. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, Department of Health and Human Services, 1996 Update.

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